

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001200	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 07/26/2023
NAME OF PROVIDER OR SUPPLIER: VALLEY EYE SURGICAL CENTER STATE LICENSE NUMBER: 20331501		STREET ADDRESS, CITY, STATE, ZIP CODE: 1685 VALLEY CENTER PARKWAY Suite 200 BETHLEHEM, PA 18017			
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S 0000	INITIAL COMMENT	S 0000			
	This report is the result of an onsite State licensure survey initiated on July 20, 2023, and completed offsite on July 26, 2023, at Valley Eye Surgical Center. It was determined the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Ambulatory Care Facilities, Annex A, Title 28, Part IV, Subparts A and F, Chapters 551-573, November 1999.				
S 0115		S 0115			
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE			TITLE:		(X6) DATE:

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S 0115	<p>Continued from page 1</p> <p>551.22 (2) Criteria for performance Of Pediatric Patient</p> <p>551.22. Criteria for Performance of Ambulatory Surgery on Pediatric Patients</p> <p>In addition to the criteria set forth at 551.21 (relating to criteria for ambulatory surgery), the following criteria shall apply to the performance of ambulatory surgery on children under 18 years of age.</p> <p>(2) The medical record shall include documentation that the child's primary care provider was notified by the surgeon in advance of the performance of a procedure in an ambulatory surgical facility and that an opinion was sought from the primary care provider regarding the appropriateness of the use of the facility for the proposed procedure. When such an opinion from the child's primary care provider is not obtainable, the medical record shall include documentation which explains why such an opinion could not be obtained.</p> <p>This REGULATION is not met as evidenced by:</p>	S 0115	<p>Corrective Action:</p> <p>Valley Eye Surgical Center (VESC) has revised the "Pediatrics Policy" to include language stating that prior to the date of surgery, for any individual under the age of 18, an affirmative response from that patient's PCP/Pediatrician, indicating that it is appropriate for the patient to have the procedure at Valley Eye Surgical Center, must be present on the Medical History and Physical Assessment Form (H&P).</p> <p>The policy further states that when such a statement is not present on the H&P form, the medical record shall include documentation which explains why such an opinion could not be obtained. The new policy will be approved by the board no later than 9/30/2023.</p> <p>S 0115 #2: A review was completed of all currently scheduled procedures. For any case where the patient's PCP</p>	<p>Completion Date: 08/29/2023</p> <p>Status: APPROVED</p> <p>Date: 08/30/2023</p>	

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S 0115	Continued from page 2	S 0115	<p>had already sent in the H&P, a separate note was sent to the PCP to confirm that it would be appropriate for the patient to have the scheduled procedure performed in an Ambulatory Surgical Center. Where the H&P had not yet been completed, and for all procedures involving individuals under 18 moving forward, additional language has been added to the H&P form requiring the physician to explicitly agree or disagree with the following statement: "the procedure proposed for this patient can be appropriately performed at Valley Eye Surgical Center, an Ambulatory Surgical Center."</p> <p>Receipt of this form, with an affirmative response from the PCP regarding the procedure being performed at Valley Eye Surgery Center, as an ASC, will be required prior to surgery. The response from the PCP will be scanned into the patient's electronic medical record (EMR). If for any reason VESC is unable to obtain the opinion of the PCP, there will be documentation in</p>		

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S 0115	Continued from page 3	S 0115	<p>the medical record as to why the opinion could not be obtained. All nursing and administrative staff will be educated on this requirement via 1:1 training with sign in sheet.</p> <p>Responsible Party: Director of Nursing</p> <p>Monitoring Activity: The DON or his designee will perform an audit of all pediatric charts for a period of 60 days, to ensure sustained compliance. Then, this requirement will be monitored via the Nurse Chart Audit tool. Results of the Nurse Chart Audit tool are reported to the QAPI Committee at the regularly scheduled quarterly meetings. Noncompliance will be reported to the Governing Board ("GB") by the Administrator.</p>		

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S 0115	<p>Continued from page 4</p> <p>Based on a review of facility policy, medical record review (MR) and interviews with staff (EMP), it was determined that the facility failed to notify the child's primary care physician and seek an opinion regarding the appropriateness of performing the procedure in an ambulatory surgical facility for two of two pediatric medical records reviewed (MR4 and MR9).</p> <p>Findings include:</p> <p>Review on July 20, 2023, of facility policy, "Pediatrics Policy," approved March 12, 2023, revealed the policy did not address the need for the facility to notify the PCP for an opinion regarding the appropriateness of performing the procedure in an ASF.</p> <p>1. Review on July 20, 2023, of MR4 revealed the patient's date of birth was July 21, 2018, and presented to the surgery center for a surgical procedure July 14, 2023. Further review revealed no documentation the child's primary care provider</p>	S 0115			

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S 0115	Continued from page 5 was notified by the surgeon in advance of the performance of a procedure in an ambulatory surgical facility and that an opinion was sought from the primary care provider regarding the appropriateness of the use of the facility for the proposed procedure. Further review revealed no documentation that explained why such an opinion was not obtained. 2. Review on July 20, 2023, of MR9 revealed the patient's date of birth was November 2, 2021, and presented to the surgery center for a surgical procedure July 14, 2023. Further review revealed no documentation the child's primary care provider was notified by the surgeon in advance of the performance of a procedure in an ambulatory surgical facility and that an opinion was sought from the primary care provider regarding the appropriateness of the use of the facility for the proposed procedure. Further review revealed no documentation that explained why such an opinion was not obtained.	S 0115			

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S 0115	Continued from page 6 Interview with EMP1 on July 20, 2023, at approximately 1:30 PM confirmed there was no documentation that the child's PCP was notified and an opinion sought as to the appropriateness of performing the procedure in an ASF for MR4 and MR9.	S 0115			
S 033A		S 033A			

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S 033A	Continued from page 7 553.3 (1) Governing Body Responsibilities 553.3 Governing Body responsibilities include: (1) Conforming to all applicable Federal, State, and local laws. This REGULATION is not met as evidenced by:	S 033A	Corrective Action: S033A #1 The center's current Infection Control Plan does reference nationally recognized guidelines and standards "...The Infection Prevention and Control Plan is based upon nationally recognized guidelines and standards for the prevention and control of infection, including but not limited to CDC, AORN, ASORN, AAMI, APIC, and OSHA." Additionally, while the "Multidose Ophthalmic Drops and Ointment (MODO)" policy does include the statement "when using multi-dose eye drops in a surgical facility it is acceptable for expiration dates to follow manufacturer's recommendations if multi-dose eye drops are labeled and handled per CDC guidelines," that piece of guidance was taken from one of the source documents for the MODO policy that itself referenced the CDC guidelines. That source document, which is listed as a resource on the MODO	Completion Date: 08/29/2023 Status: APPROVED Date: 08/31/2023	

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S 033A	Continued from page 8	S 033A	<p>policy, is titled "Reducing Topical Waste in Ophthalmic Surgery" and was a Multisociety Position Paper published by the American Society of Cataract and Refractive Surgery, The American Academy of Ophthalmology, The American Glaucoma Society, and the Outpatient Ophthalmic Surgery Society." The CDC guidance referenced in that article is: "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care ("Guide")" Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases; Division of Healthcare Quality Promotion, Version 2.3 - September 2016. https://www.cdc.gov/infectioncontrol/pdf/outpatient/guide.pdf. The Guide referenced above indicates that before administering eye drops, hand hygiene must be performed correctly. In sum, the MODO policy is stating that it is</p>		

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S 033A	Continued from page 9	S 033A	acceptable for expiration dates to follow manufacturer's recommendations if multi-dose eye drops are labeled and the person handling the eye drops has performed correct hand hygiene procedures. The other resource referenced in the MODO policy is the American Society of Ophthalmic Registered Nurses ("ASORN") Recommended Practice: Use of Multi-dose Medications. Accessed March 11, 2022. https://asorn.org/professional/resources/policies_and_recommendations/asorn_recommended_practice_use_of_multi-dose-medication . This article states "Eyedrop medications labeled as multi-dose may be used for more than one patient if, and only if, aseptic technique and standard precautions are followed." The article goes on to list very specific steps as the appropriate aseptic technique and standard precautions for Multi-dose Ophthalmic Drops and Ointments.		

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S 033A	Continued from page 10	S 033A	<p>VESC believes this guidance supports the use of multi-dose eyedrops if administered per the proper procedures. A revised Infection Control Plan is being written to include these explicit procedures. It will be completed and submitted for approval by September 30, 2023. All impacted staff will be re-trained on these procedures within 30 days of the Department of Health approval.</p> <p>Responsible Party: Director of Nursing/Infection Control Nurse</p> <p>Monitoring Activity: The DON/Infection Control Nurse will present the revised Infection Control Plan (ICP) to the Infection Control Committee (ICC) upon approval from the DOH and ensure the inclusion of multi-use medications is present. The ICC will present a report to the QAPI Committee at the quarterly meeting. The GB will have final approval of the Infection Control Plan.</p>		

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S 033A	Continued from page 11	S 033A	<p>S033A#2</p> <p>Each page of the current IC plan has 1/10 in the bottom left corner of the page; that is the date the plan was implemented. The facility has an email of acceptance for their IC Plan dated 1/29/2010. The center will attach a copy of the acceptance email to the current plan. The revised plan will clearly state the date of development, the date of approval by the IPC Committee and the date of approval by the GB. In the current Infection Control Plan under the heading "Other Actions" (pg. 10) #3 states "Teaching – All advisories provided under Section 405(B) (4) received by this ASC related to appropriate infection control and anti-transmission topics for this ASC and information received from other professional sources, will be reviewed in inservice education programs, forwarded to the medical staff, and posted for review by employees." This document was submitted via email on 7/25/23.</p>		

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S 033A	Continued from page 12	S 033A	<p>The revised version of the Infection Control plan does include the procedure for the distribution of the Patient Safety Advisories, as well as multi-use eye drops and ointments. The revised version of the Infection Prevention and Control Plan will be completed and submitted to the DOH for review by 9/30/23. The center will continue to distribute the Patient Safety Advisories to the staff in the common area.</p> <p>Responsible Party: Director of Nursing</p> <p>Monitoring Activity: The DON/Infection Control Nurse will present the revised ICP to the ICC Committee upon approval from the DOH and ensure the inclusion of Patient Safety Advisories Education is present, as well as multi use ophthalmic medications. The Infection Control Committee will present a report to the QAPI Committee at the quarterly meeting. The GB will have final approval of</p>		

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S 033A	Continued from page 13	S 033A	the Infection Prevention and Control Plan.		

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S 033A	Continued from page 14 Based on review of facility documents and interview with staff (EMP), it was determined the facility failed to conform to applicable State laws. Valley Eye Surgery Center was not in compliance with the following State law: "Act 52 of 2007, Medical Care Availability and Reduction of Error (MCARE) Act Chapter 4. Health Care-Associated Infections 40 P.S. § 1303.403. Infection control plan (a) Development and Compliance. - Within 120 days of the effective date of this section, a health care facility and an ambulatory surgical facility shall develop and implement an internal infection control plan that shall be established for the purpose of improving the health and safety of patients and health care workers and shall include ... (2) Effective measures for the detection, control, and prevention of health-care-associated infections ... (8) The procedure for distribution of advisories issued under section 405(b)(4) so as to ensure easy access in	S 033A			

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S 033A	<p>Continued from page 15</p> <p>each health care facility for all administrative staff, medical personnel and health care workers.</p> <p>This is not met as evidenced by:</p> <p>Based on review of facility documents and interview with staff (EMP), it was determined the facility failed to ensure their multi-use medications followed their established infection control plan and failed to provide a procedure for the distribution of the Patient Safety Advisories.</p> <p>Findings include:</p> <p>1. Review on July 20, 2023, of the facility document "Valley Eye Surgical Center, Infection Prevention and Control Plan," not dated, revealed "... The purpose of the Valley Eye Infection Control Plan is to ensure the health, safety, and protection against healthcare associated infections ... and to comply</p>	S 033A			

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S 033A	Continued from page 16 with the requiements of ACT 52 concerning infection prevention and control in healthcare facilties ... The infection prevention and control plan is based upon nationally recognized guidelines and standards ... CDC ..." Review on July 20, 2023, of facility policy "Multidose Ophthalmic Drops and Ointment" approved March 1, 2023, revealed "Resources ... 'Reducing Topical Drug Waste in Ophthalmic Surgery' Multisociety Position Paper (opinion essay) ... when using multi-dose eye drops in a surgical facility it is acceptable for expiration dates to follow manufacturer's recommendations if multi-dose eye drops are labeled, handled per CDC guidelines ..." A request was made on July 25, 2023, at approximately 2:25 PM to EMP1 for the CDC guidelines that support the facility's policy. None provided.	S 033A			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001200	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 07/26/2023
NAME OF PROVIDER OR SUPPLIER: VALLEY EYE SURGICAL CENTER STATE LICENSE NUMBER: 20331501		STREET ADDRESS, CITY, STATE, ZIP CODE: 1685 VALLEY CENTER PARKWAY Suite 200 BETHLEHEM, PA 18017			
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S 033A	Continued from page 17 2. Review on July 25, 2023, of facility document "Valley Eye Surgical Center Infection Control Plan" not dated, revealed no provisions for the distribution of the Patient Safety Advisories. Interview on July 25, 2023, with EMP2 at approximately 2:40 PM confirmed they did not have the CDC guidelines for the use and handling of multi-dose eye drops and confirmed the infection control plan did not include provisions for the distribution of the Patient Safety Advisories.	S 033A			
S 312G		S 312G			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001200	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED: 07/26/2023	
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S 312G	Continued from page 18 553.12 (b)(6) Implementation 553.12 (b) The following are the minimal provisions for the patient's bill of rights: (6) The patient has the right to expect emergency procedures to be implemented without unnecessary delay. This REGULATION is not met as evidenced by:	S 312G	Corrective Action: The Policy "Patients' Rights and Responsibilities" has been revised to include the statement "The patient has the right to expect emergency procedures to be implemented without unnecessary delay" The policy was approved by the GB on 8/8/2023. The statement was also added to the Patients' Rights document that is posted in the waiting room and available to patients upon admission. Responsible Party: Administrator Monitoring Activity: The patient acknowledgement of receipt of the Patients Bill of Rights and Patient Rights and Responsibilities has been added to the chart audit tool and will be monitored quarterly and reported to the QAPI Committee. The Administrator will report any noncompliance to the GB.	Completion Date: 08/29/2023 Status: APPROVED Date: 08/30/2023	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001200	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 07/26/2023
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S 312G	Continued from page 19 Based on review of facility policies, observation and interview with staff (EMP), it was determined the facility failed to ensure a patient's rights for the implementation of emergency procedures without unnecessary delay. Findings include: Review on July 21, 2023, of facility document "Rights of Patients" approved March 12, 2023, revealed no provision it was the right of a patient to expect emergency procedures to be implemented without unnecessary delay. Interview on July 26, 2023, at approximately 9:00 AM with EMP1 confirmed the implementation of emergency procedures without unnecessary delay is not included in the facility's Patient Rights document.	S 312G			

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S 6110		S 6110			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001200	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 07/26/2023
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S 6110	Continued from page 21 561.1 Drugs & Biologicals CHAPTER 561 - PHARMACEUTICAL SERVICES 561.1 Drugs and Biologicals The ASF shall provide drugs and biologicals in a safe and effective manner to meet the needs of patients, and to adequately support the organization's clinical capabilities commensurate with their licenses classification, in accordance with accepted ethical and professional practice and applicable State and Federal law, including the Pharmacy Act (63 P.S. 390-1 -390.13), 49 Pa. Code Chapter 27 (relating tot he State Board of Pharmacy), The Controlled Substance, Drug, Device and Cosmetic ACT (35 P.S. 780-101-780-144) and Chapter 25 (relating to controlled substances, drugs, devices and cosmetics). This REGULATION is not met as evidenced by:	S 6110	Corrective Action: A new 700 Stat Kit has been ordered to replace the existing one. The center has created a new Medication Expiration Checklist which includes the Stat Kit 700. A staff member will check this kit monthly for medication and supply expiration dates and remove and replace any items that will expire within the next 60 days. Responsible Party: Director of Nursing Monitoring Activity: The DON will complete a documented monthly review of the Medication Expiration Checklist and will perform a surprise inspection of the actual medications monthly for the next 120 days to verify that the current process is functioning appropriately. The Medication Expiration Checklist and results of the DON's inspections will be reviewed at the quarterly QAPI Committee meetings.	Completion Date: 08/31/2023 Status: APPROVED Date: 09/07/2023	

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S 6110	Continued from page 22	S 6110	<p>The Administrator will report any noncompliance to the GB.</p> <p>08/31/2023 Update:</p> <p>The following medications were noted as missing from the Stat Kit during the survey: diphenhydramine caplets, clonidine tablets, aspirin tablets, nalbuphrine ampules, solu-cortef vials, dextrose 50% prefilled syringes and epinephrine 1:10,000/ml with intercardiac needle. A new Stat Kit 700 has been ordered to fully replace the existing item and is scheduled for delivery on September 5, 2023. To ensure the deficiency was corrected while waiting for the new kit to arrive, the following medications were able to be replaced promptly: diphenhydramine caplets, aspirin, solu-cortef, and Epinephrine. Prefilled dextrose syringes are on backorder, so a 250 ml bag of dextrose was placed in the kit, as</p>		

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S 6110	Continued from page 23	S 6110	<p>was acceptable for the code carts. Nalbuphrine is currently on backorder and clonidine was not on the formulary for VESC, so it was not able to be readily replaced. However, VESC has Toradol and Fentanyl that can be used in place of Nalbuphrine and Hyrdalazine that can be used in place of clonidine in stock and ready for use A breakaway lock has been placed on the existing Kit and will be placed on the new kit once it arrives. A staff member will check the kit daily for medication and supply quantities and expiration dates and will remove and replace any items that will expire within 60 days and will replace any items whose supplies have been exhausted.</p> <p>Responsible Party: DON</p> <p>Monitoring Activity:</p> <p>The DON will complete a documented monthly review of the Medication Expiration Checklist and will perform a surprise inspection of the actual medications monthly for</p>		

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S 6110	Continued from page 24	S 6110	the next 120 days to verify that the current process is functioning appropriately. The Medication Expiration Checklist and results of the DON's inspections will be reviewed at the quarterly QAPI Committee meetings. The Administrator will report any noncompliance to the GB.		

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S 6110	<p>Continued from page 25</p> <p>Based on observation and interview with staff, it was determined the facility failed to maintain a supply of medications for emergency resuscitation.</p> <p>Findings include:</p> <p>On July 20, 2023, a policy was requested to EMP1 for the use and maintenance of the [name of kit] 700 Stat Kit. None provided.</p> <p>Observation on July 20, 2023, of the pre-operative/post-operative recovery area at approximately 12:30 PM revealed a black case (stat kit) that contained emergency medications and supplies. Further observation revealed the designated spaces for the following medications were empty: diphenhydramine caplets, clonidine tablets, aspirin tablets, nalbuphrine ampules, solu-cortef vials, dextrose 50% prefilled syringes, and epinephrine 1:10,000/ml with intercardiac needle.</p>	S 6110			

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S 6110	Continued from page 26 Review on July 20, 2023, of facility document "Consultant Pharmacy Report" dated June 19, 2023, revealed "... the following medications are missing ... diphenhydramine caplets, clonidine tablets, aspirin tablets, nalbuphrine ampules, solu-cortef vials, dextrose 50% prefilled syringes ..." Interview on July 20, 2023, at approximately 12:30 PM with EMP1 confirmed the emergency medications in the stat kit were missing and confirmed they were aware of the missing medications based on their review of the pharmacy consultation report.	S 6110			
S 6128		S 6128			

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S 6128	Continued from page 27 561.15 Locked Storage 561.15 Locked Storage Special locked storage space shall be provided to meet requirements for storage of controlled substances, alcohol and other prescribed drugs as set forth in Chapter 25 (relating to controlled substances, drugs, devices and cosmetics) and 49 Pa Code 27.16 (4) and 27.17 (relating to construction requirements and security for Schedule II controlled substances). This REGULATION is not met as evidenced by:	S 6128	S 6128 #1 Corrective Action: A new policy has been drafted titled "Malignant Hyperthermia Cart." This policy states that the MH Cart is equipped with a breakaway lock to prevent unauthorized access and references the newly created Malignant Hyperthermia Cart checklist which will be used to monitor the cart and contain the number for the breakaway lock. S 6128 #2: Corrective Action: VESC has purchased a new Code Cart which allows for the installation of a breakaway lock. The new cart has been installed and is checked and logged daily on the Monthly Crash Cart Checklist. The Monthly Crash Chart Checklist includes a space to log the number on the breakaway lock. The OR Supervisor or designee, will check the Daily Code Cart checklist to ensure it has been completed in its entirety.	Completion Date: 08/29/2023 Status: APPROVED Date: 08/30/2023	

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S 6128	Continued from page 28	S 6128	<p>S 6128 #3: Corrective Action As referenced above, the MH Cart has been equipped with a breakaway lock. The center has created a daily MH Cart Checklist with a space to log the number on the breakaway lock. The OR Supervisor will check the MH Cart checklist daily to ensure it has been completed in its entirety.</p> <p>Responsible Party: Director of Nursing</p> <p>Monitoring Activity: At the end of the month, the DON will review the Monthly Crash Chart Checklist and MH Cart Checklist to ensure it has been completed in its entirety. Noncompliance will be reported to the QAPI Committee by the DON and to the GB by the Administrator.</p>		

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S 6128	<p>Continued from page 29</p> <p>Based on observation, review of facility policy, and interview with staff (EMP) it was determined the facility failed to follow its established policy to ensure medications were stored securely to prevent unauthorized access.</p> <p>Findings include:</p> <p>Review on July 20, 2023, of facility policy "Code Cart" approved March 12, 2023, revealed "...A breakaway lock will secure the contents of the cart but not restrict immediate access during a medical emergency ..."</p> <p>A request was made on July 20, 2023, to EMP1 for a policy that restricted unauthorized access to the malignant hyperthermia cart. None provided.</p> <p>1.Observation on July 20, 2023, at approximately 10:00 AM of the crash cart located in the operating</p>	S 6128			

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S 6128	Continued from page 30 room hallway revealed the cart was unlocked. Further observation revealed the type of lock used was a keypad lock and was sitting on top of the crash cart. 2.Observation on July 20, 2023, at approximately 10:00 AM of the blue malignant hyperthermia cart located in the operating room hallway revealed the cart was unlocked. Further observation revealed the type of lock used was a keypad lock and was sitting on top of the crash cart. Interview on July 20, 2023, with EMP1 confirmed the code cart and the hyperthermia cart were unlocked at the time of the observation and confirmed the type of locks currently in use were not the breakway type to allow immediate access to the carts. Interview on July 20, 2023, with EMP2 confirmed there was no policy for securing the hyperthermia	S 6128			

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S 6128	Continued from page 31 cart to restrict unauthorized access.	S 6128			
S 6142		S 6142			

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S 6142	Continued from page 32 561.25 Distressed drugs, devices and cosmetics 561.25 Distressed drugs, devices and cosmetics Drugs, devices and cosmetics which are outdated, visibly deteriorated, unlabeled or inadequately labeled, recalled, discontinued or obsolete shall be identified by the licensed pharmacist or responsible practitioner and shall be disposed of in compliance with applicable Commonwealth and Federal regulations. This REGULATION is not met as evidenced by:	S 6142	Corrective Action: All expired medications were removed, discarded and replaced. To add additional controls to the already existing medication management processes, the ASC has adopted an enhanced monitoring plan: Each area/cart that contains medications and supplies that contain an expiration date will be checked during the last operating week of each month. Any medications or supplies that will be expiring within the next 60 days will be marked with a label "Expiring Soon" Medications in the Code and Malignant Hyperthermia carts as well as the Stat Kit 700, will be removed from those areas two months prior to the expiration date and replaced with new medications from the supply. These activities will be noted on the newly created Monthly Medication Expiration Checklist. The	Completion Date: 08/29/2023 Status: APPROVED Date: 08/30/2023	

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S 6142	Continued from page 33	S 6142	<p>department Manager will review the Medication Expiration Checklist each month.</p> <p>Responsible Party: Director of Nursing</p> <p>Monitoring Activity: The DON will complete a documented monthly review of the Medication Expiration Checklist and will perform a surprise inspection of the actual medications monthly for the next 120 days to verify that the current process is functioning appropriately. This will be reported to the QAPI Committee at the quarterly meetings. Any noncompliance will be reported to the GB by the Administrator.</p>		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001200	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 07/26/2023
NAME OF PROVIDER OR SUPPLIER: VALLEY EYE SURGICAL CENTER STATE LICENSE NUMBER: 20331501		STREET ADDRESS, CITY, STATE, ZIP CODE: 1685 VALLEY CENTER PARKWAY Suite 200 BETHLEHEM, PA 18017			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE	(X5) COMPLETE DATE	
S 6142	<p>Continued from page 34</p> <p>Based on review of facility policy, facility documents, observation and interview with staff (EMP) it was determined the facility failed to ensure expired medications were removed from the crash cart, malignant hyperthermia cart and stat kit.</p> <p>Findings include:</p> <p>Review on July 20, 2023, of facility policy "Expired Medications," approved March 12, 2023, revealed "In accordance with professional standards of pharmacy practice, no outdated or deteriorated medications shall be kept in stock at the Center ..."</p> <p>1.Observation on July 20, 2023, at approximately 10:00 AM of the operating room crash cart revealed the following expired medications: furosemide vial 40mg/4ml-expired July 1, 2023, hydralazine hydrochloride 2mg/ml 1ml vial-expired June 2023, adenosine 6mg/2ml 2ml vial -expired June 2023, Lidocaine HCL 2% 50ml vial-expired July 1, 2023.</p>	S 6142			

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S 6142	<p>Continued from page 35</p> <p>2.Observation on July 20, 2023, at approximately 10:00 AM of the operating room malignant hyperthermia cart revealed the following medication was expired: furosemide 4mg/4ml-expired July 1, 2023.</p> <p>3.Observation on July 20, 2023, at approximately 12:30 PM of the [name] 700 stat kit revealed the following medications were expired: furosemide 4mg/4ml vial-expired July 1, 2023, amiodarone 50mg/ml-expired July 2023. EMP1 confirmed the amiodarone was an expired medication at the time of the observation (see interview below).</p> <p>Interview on July 20, 2023, with EMP1 confirmed the location of the medications and confirmed all the medications observed were expired during the observation tour of the facility.</p>	S 6142			

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S 6142	Continued from page 36	S 6142			
S 6734		S 6734			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001200	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 07/26/2023
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S 6734	Continued from page 37 567.11 (7) Operating Suite Equipment 567.11 Operating suite equipment The operating suite shall be adequately equipped with age appropriate equipment for the types of procedures to be performed and the recovery area shall be adequately equipped for the proper care of postanesthesia recovery of surgical patients. All equipment and supplies shall be age and size appropriate for the patients treated. The following equipment shall be available in the operating suite and recovery area: (7) Tracheostomy and necessary pulmonary reexpansion supplies This REGULATION is not met as evidenced by:	S 6734	Corrective Action: The facility has ordered 14gauge needle with single valve to be placed on the Code Cart for pulmonary reexpansion. The facility has cricothyrotomy kits in every anesthesia cart and in the difficult airway box. An additional kit has been purchased for the Code Cart. The staff responsible for updating the Code Cart log has been re-trained to ensure they are including the emergency tracheostomy and pulmonary expansion supplies in the monthly review when opening the cart to check for contents and expiration dates. The OR Supervisor will review the Code Cart log daily to ensure it is completed in its entirety; The Code Cart will be opened monthly and the contents checked for availability and expiration dates.	Completion Date: 08/29/2023 Status: APPROVED Date: 08/31/2023	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001200	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 07/26/2023
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S 6734	Continued from page 38	S 6734	Responsible Party: Director of Nursing Monitoring Activity: The DON will review the Code Cart checklist at the end of each month and report to the QAPI Committee at the quarterly meeting. The Administrator will report any noncompliance to the GB.		

Pennsylvania Department of Health

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S 6734	<p>Continued from page 39</p> <p>Based on review of facility policies and procedures, observations, and interview with staff (EMP), it was determined that the facility failed to ensure emergency pulmonary re-expansion supplies were readily available in the operating suite.</p> <p>Findings include:</p> <p>Review on July 20, 2023, of facility policy "Code Cart," approved March 12, 2023, revealed "... The facility will maintain a supply of drugs in the Emergency Medication Cart (Crash cart) as determined by the Credentialing/Quality Committee and approved by the Board of Managers ..."</p> <p>Review on July 20, 2023, of facility document "Monthly Crash Cart Checklist," not dated, revealed no documentation emergency tracheostomy and necessary pulmonary expansion supplies were readily available in the crash cart.</p>	S 6734			

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S 6734	Continued from page 40 Observation on July 20, 2023, at approximately 10:00 AM of the facility's crash cart revealed emergency tracheostomy and necessary pulmonary expansion supplies were not in the crash cart. Interview on July 20, 2023, at approximately 10:15 AM with EMP1 confirmed the crash cart did not contain emergency tracheostomy and necessary pulmonary expansion supplies. Interview on July 20, 2023, with EMP3 at approximately 10:45AM confirmed the Monthly Crash Cart Checklist was a list of all medications and supplies approved by the governing board for the emergency crash cart.	S 6734			
S 6744		S 6744			

Pennsylvania Department of Health

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S 6744	Continued from page 41 567.41 MAINTENANCE SERVICE - Principle 567.41 Principle The ASF shall be equipped, operated and maintained to sustain its safe and sanitary characteristics and to minimize health hazards in the ASF for the protection of patients and employees. This REGULATION is not met as evidenced by:	S 6744	Corrective Action: The facility had the preventive maintenance for the Constellation (2 systems)) was completed on 8/2/23. It is scheduled to be performed twice yearly. The facility had the preventive maintenance performed on the Centurian Vision System (s) (3 systems) on 7/27/23. The preventive maintenance is to be performed annually. The facility had the preventive maintenance performed on the Femto Laser LensX on 8/23/23. Moving forward it is scheduled to be performed twice a year. The facility has implemented a Preventive Maintenance Spreadsheet which will be reviewed monthly by the OR Supervisor to ensure preventive maintenance is completed promptly when due. Responsible Party: Director of Nursing	Completion Date: 08/29/2023 Status: APPROVED Date: 08/30/2023	

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S 6744	Continued from page 42	S 6744	Monitoring Activity: The Preventive Maintenance Spreadsheet will be reviewed by the DON monthly and report to the QAPI Committee quarterly. Noncompliance will be reported to the GB by the Administrator.		

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S 6744	<p>Continued from page 43</p> <p>Based on review of facility documents, observation, and interview with staff (EMP), it was determined the facility failed to follow its established policy for preventative maintenance of equipment used to perform surgical procedures.</p> <p>Findings include:</p> <p>Review on July 20, 2023, of facility policy "Systems Maintenance" approved March 12, 2023, revealed "... Equipment used on or for patients will be checked by a qualified biomedical person according to the manufacturer's instruction. Documents will be kept on each item including testing performed and the results ..."</p> <p>1.Observation on July 20, 2023, of OR 2 at 10:40 AM revealed surgical equipment identified as "Constellation" used to perform vitrectomy procedures. Further review of the preventive maintenance tag located on the machine revealed the</p>	S 6744			

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S 6744	<p>Continued from page 44</p> <p>most recent preventative maintenance occurred on June 2020.</p> <p>2.Observation on July 20, 2023, of OR 1 at 10:50 AM revealed surgical equipment identified as "Centurian Vision System" phaco machine used to perform cataract surgeries. Further observation of the preventive maintenance tag located on the machine revealed no documentation preventative maintenance was performed.</p> <p>3.Observation on July 20, 2023, of OR 1 at 10:55 AM revealed surgical equipment identified as "Femto Laser Lensx" used to perform ocular laser surgery. Further observation of the preventive maintenance tag located on the machine revealed no documentation preventative maintenance was performed.</p> <p>Interview on July 20, 2023, with EMP2 confirmed there was no documentation preventative maintenance and testing was performed on the above surgical equipment.</p>	S 6744			

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S 6744	Continued from page 45	S 6744			



Certified End Page

VALLEY EYE SURGICAL CENTER
STATE LICENSE NUMBER: 20331501
SURVEY EXIT DATE: 07/26/2023

**I Certify This Document to be a True and Correct Statement of Deficiencies and
Approved Facility Plan of Correction for the Above-Identified Facility Survey**

A handwritten signature in black ink that reads "Jeane Parisi".

Jeane Parisi
Deputy Secretary for Quality Assurance

A handwritten signature in black ink that reads "Debra L. Bogen MD".

Debra L. Bogen, MD, FAAP
Acting Secretary of Health



THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY